

## A Doctor's Guide to Stent Implantation



Must Check

**VISION™**

Coronary Stent Family

**COBALT CHROMIUM**

1314113-0000

This booklet is provided by Guidant Corporation's, Vascular Intervention Group. For more information, visit [www.guidant.com](http://www.guidant.com).

The more you know about your condition and its treatment, the better. This brochure has been prepared to answer some of the questions you may have. As you read on, you might discover some issues that you would like to discuss in more detail. Don't hesitate to take them up with your doctor or nurse – you'll find a place in the back for your notes.

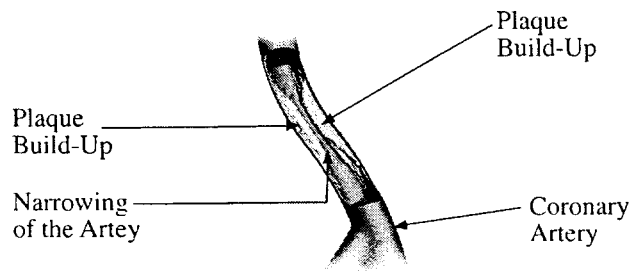
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## CORONARY ARTERY DISEASE

### Its Causes

Coronary Artery Disease is caused by a build-up of fatty substances like cholesterol. Where they collect in the artery, the internal lining thickens, the artery narrows and blood flow slows. These fatty build-ups are sometimes called plaque or lesions.



### Risk Factors

Any of the following risk factors may increase your chances of developing Coronary Artery Disease:

- Diabetes
- Smoking
- Stress
- Obesity (being overweight)
- High Blood Pressure
- Relative with the Disease
- Lack of Exercise

### **Its Effects**

Your heart is a muscle. To function efficiently, it needs a constant supply of oxygen and nutrient-rich blood. Two main arteries and a network of vessels covering the surface of the heart carry the blood supply. If these coronary arteries become partially blocked by fatty deposits, the heart does not receive enough oxygenated blood. And when physical or psychological stress creates a need for even more oxygen and nutrients, the heart muscle is unable to respond. This is the point at which you're likely to experience angina or chest pain – and if the condition is not treated, a myocardial infarction or a heart attack could follow.

### **Reaching a Diagnosis**

#### ***The Exercise Electrocardiogram***

One of the most common forms of diagnostic testing is the Exercise Electrocardiogram (ECG) or Stress Test. During closely controlled exercise, the changes of your heart's electrical activity will be carefully monitored. If there are any abnormalities, your doctor may recommend further tests.

#### ***The Coronary Angiogram***

Before a final decision regarding your diagnosis and / or treatment is made, you may be asked to undergo a Coronary Angiogram. A special dye / contrast material is injected into the coronary arteries and x-rays are taken. This procedure is performed under local anesthetic in a cardiac catheterization laboratory, which is a special room

in the hospital containing an x-ray machine to perform this type of procedure. The dye shows up on the x-rays, revealing the arteries and the presence of any narrowing and blockages.

### **YOUR TREATMENT OPTIONS**

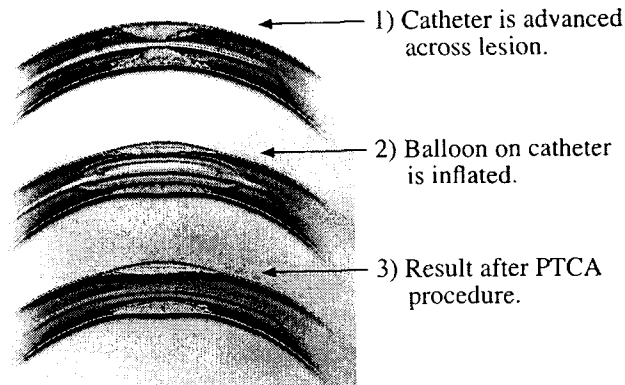
Once a diagnosis has been reached, your doctor will recommend the most appropriate form of treatment. Treatment options include medications, lifestyle changes, angioplasty with or without stent placement, and surgery.

#### **Angioplasty**

This opens blocked arteries. You may also hear it referred to as PTCA (percutaneous transluminal coronary angioplasty). It is performed under local anesthetic in a cardiac catheterization laboratory. A small puncture is made, usually in the groin or arm. A sheath is inserted into the opening and a guiding catheter is fed through the sheath into your artery. X-ray contrast is injected through the catheter so that your doctor can see your coronary arteries on a fluoroscope -- an x-ray machine with a monitor screen to view the arteries.

1) The doctor guides a vascular catheter with a small balloon through a blood vessel to the narrowed section of the artery. By watching the progress of this catheter on the fluoroscope, the doctor is able to maneuver it into the blocked coronary artery. 2) When the balloon is inflated, it pushes out against the wall of the artery and compresses the plaque.

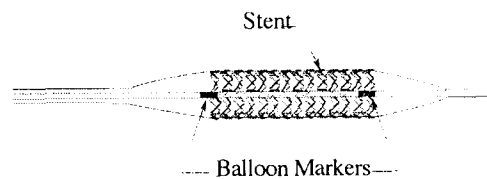
3) This makes the inside of the blood vessel larger and improves the blood flow.



### **The Stent Procedure**

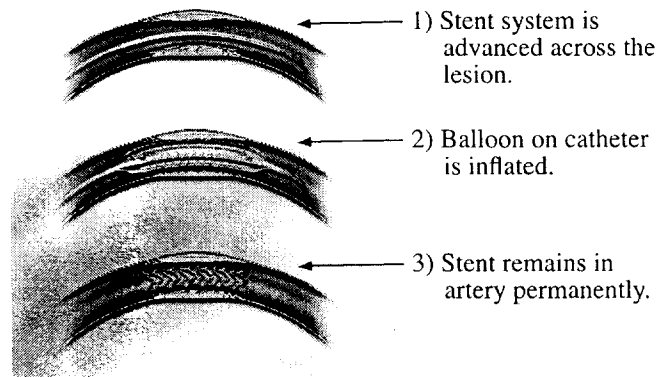
Unfortunately, arterial fatty deposits have a tendency to rebuild over time. To reduce the chances of this happening, your doctor may recommend the placement of a coronary stent. It can be inserted during the same procedure as soon as the angioplasty has been completed.

The Guidant MULTI-LINK VISION™ Coronary Stent Family consists of small, latticed cobalt chromium tubes that are introduced into arteries via balloon catheters.



1) The doctor maneuvers the catheter of the stent system across the area of blockage and inflates the balloon. 2) This causes the stent to expand, pressing it against the artery wall.

3) Once the balloon has been deflated and withdrawn, the stent stays in place permanently – holding the blood vessel open, improving the flow of blood and relieving the symptoms of coronary artery disease.



### **Know the Benefits & the Risks**

Talk to your physician about the benefits and the risks in this type of procedure. As with any invasive procedure, the likelihood of occurrences is dependent on many conditions that are specific to each patient. Use of this device carries risks such as: vascular complications and / or bleeding events, heart attack, chest pain, irregular heartbeat, death, a tear in the artery wall, a reaction to the contrast material or medication during the procedure, an

obstruction of the artery (by air, tissue or blood clot), emergency bypass surgery, abnormal discharge of blood requiring a transfusion, low or high blood pressure, infection, decreased blood supply to the heart muscle, puncture of the coronary artery, an enlargement of the artery wall at the insertion site that gives the impression of an aneurysm due to a weakness of the artery wall, renarrowing, obstruction, or blood clotting of the area in which the stent is placed preventing or reducing the flow of blood to the heart, involuntary contraction of the artery, stroke, total blockage of the coronary artery. Your physician can help to explain these risks.

Outcome (beyond 9 months) for this permanent implant is unknown at present.

The Guidant MULTI-LINK VISION™ Stent is not intended for use in patients who cannot tolerate blood-thinning medications (also called anti-platelet or anti-coagulant therapy).

Persons allergic to L-605 cobalt chromium (CoCr) alloy may suffer an allergic reaction to this implant.

Stent placement should only be performed at hospitals where emergency coronary artery bypass graft surgery can be readily performed.

Subsequent blockage of the artery with the stent may require repeat dilatation. The long-term outcome following repeat dilatation of stents is unknown at present.



When multiple stents are required, stent materials should be of similar composition. Placing multiple stents of different metals in contact with each other may increase the potential for corrosion.

### **PREPARING FOR YOUR STENT**

In the days prior to your treatment, make sure you:

- Take all of your prescribed medicines
- Tell your doctor if you are taking any other medication
- Tell your doctor if, for any reason, you cannot take aspirin
- Make sure your doctor knows about any allergies you have
- Refrain from eating or drinking after midnight on the night before your treatment
- Follow all instructions given to you by your doctor or nurse

You may be given a mild sedative to help you relax, but you will not be put to sleep. There are two reasons for this. First, most people find they can cope quite well with any discomfort they experience. Secondly, your doctor may need to ask you to take a deep breath while x-rays are being taken to improve the quality of the pictures.

The procedure usually lasts about 90 minutes, during which time your doctor will ask you to remain very still. For the most part, you will be comfortable – but you may feel some pressure

or chest pain when the balloon is inflated. This is normal and will quickly fade when the balloon is deflated again.

### **MAKING A SWIFT RECOVERY**

Immediately after the procedure, you'll be returned to a special observation unit, where your heart rhythm, blood pressure and puncture site will be monitored closely.

During your stent implantation, you will have been given an anti-coagulant or blood thinner. Its effects will take a few hours to wear off.

Once you are back in your room, you may be asked to drink lots of fluids to flush the contrast out of your system as quickly as possible.

If you have a puncture site in your groin, you'll have to stay in bed for several hours after the procedure, keeping the relevant leg straight and the insertion site immobile.

You may need to stay in the hospital for 1 to 2 days and then you will be discharged into the care of your doctor. Make sure you contact your doctor or the hospital immediately if you experience any discomfort, pain or bleeding once you get home.

## **GETTING ON WITH LIFE**

To begin with, you will have to return for periodic check-ups. You may be asked to undergo a post-procedure exercise electrocardiogram or angiogram. Regular periodic check-ups will follow to monitor your progress – so please be sure to keep these appointments. Your doctor may also prescribe medication to assure a quick and healthy recovery. Be sure to follow your doctor's instructions carefully and take all your medications according to his / her instructions.

Provided you get into the habit of making healthy lifestyle choices, you should soon be fit enough to pick up where you left off. If you have had a stent implanted, it will not limit your activities in any way but you should consult your doctor before you do anything physically demanding. Tell any doctor that treats you that you have a coronary stent implant, and keep your stent implant card with you at all times.

If anything you have read has raised further questions regarding the procedure, now is the time to discuss them with your doctor. And please remember, many thousands of people who have undergone angioplasty and stent implantation are leading full, active lives as a result.

## **DEFINITION OF MEDICAL TERMS**

**Angina** – chest pain caused by an inadequate supply of blood to the heart

**Angioplasty** – a procedure to open a blocked artery

**Anti-coagulant** – a medication to prevent or slow blood clotting

**Atherosclerosis** – an accumulation of fatty deposits in an artery

**Balloon** – an inflatable device used for dilating the coronary artery

**Cardiac Catheterization Laboratory** – area of the hospital where minimally invasive procedures like angiograms and angioplasty are performed

**Catheter** – a tube through which fluids or objects can be introduced or removed from the body

**Coronary Arteries** – of, relating to, or being the arteries of the heart

**Fluoroscope** – an x-ray monitor that reveals the arteries of the heart

**Local Anesthetic** – a substance used to numb the groin area

**Myocardial Infarction (MI)** – an injury to the heart caused by lack of blood flow from a coronary artery to the heart muscle

**Percutaneous** – performed through the skin

**Stent** – small metallic scaffold that is expanded in the artery to make a larger channel for improved blood flow; keeps the artery from collapsing

**Transluminal** – through the inside opening of a vessel or artery

**NOTES:**

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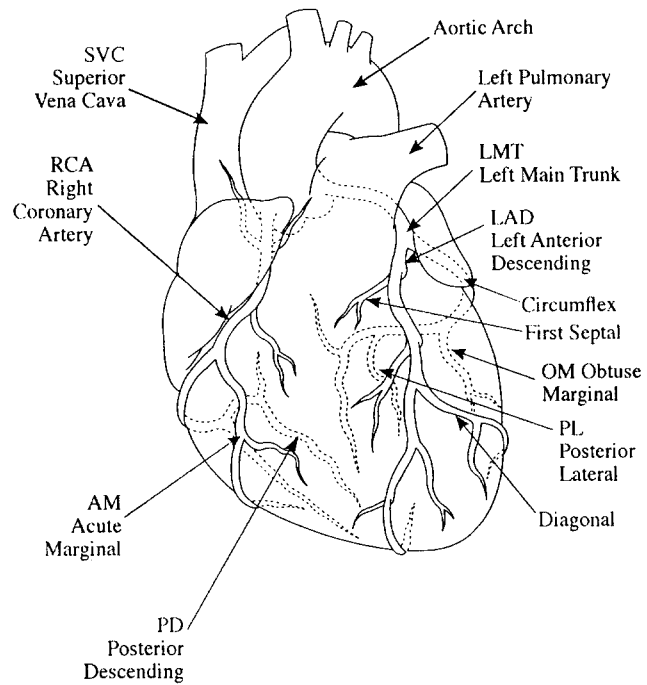
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## CORONARY VASCULATURE



## FOR YOUR RECORDS

It is recommended that you talk with your health care professional about stents and magnetic resonance imaging (MRI). Further information on MRI safety with cobalt chromium stents can be found in the *Instructions for Use* accompanying the device, or by calling Customer Service at 1-800-227-9902.

*Have your doctor or appropriate healthcare professional complete this section:*

Patient Name \_\_\_\_\_

Date of Implant \_\_\_\_\_

Site of Implant \_\_\_\_\_

Implanting Physician \_\_\_\_\_

Hospital \_\_\_\_\_

Address \_\_\_\_\_

Telephone Number \_\_\_\_\_

Primary Physician \_\_\_\_\_

Product Part Number \_\_\_\_\_

Product Lot Number \_\_\_\_\_

Guidant Corporation is a global leader in the advancement of medical technologies for the treatment of cardiovascular and vascular disease. Our devices help patients return to active and productive lives. To date, more than seven million patients worldwide have been treated with Guidant products.

## **GUIDANT**

**Guidant Corporation**  
**Santa Clara, CA 95054-2807 USA**  
**Temecula, CA 92591 USA**  
**Tel: 800-227-9902**  
**Fax: 909-914-2534**

**Guidant NV / SA**  
**European Headquarters**  
**B-1831 Diegem, Belgium**  
**Tel: 32-2-714-14-11**  
**Fax: 32-2-714-14-12**

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***Please carry this card at all times.***

***Show it to any medical personnel who may be treating you.***

### **Stent Patient Implant Card**

Patient Name	Date of Birth
Implanting Physician's Name	Phone Number
Hospital Name	
City/State	Date of Implant

**PLEASE CARRY YOUR CARD AT ALL TIMES.**

This patient may be receiving anti-platelet therapy. Please do not stop without consultation. The Guidant MULTI-LINK VISION Coronary Stent has been shown to be MRI safe immediately following implantation at field strengths of 1.5 tesla or less, a maximum spatial gradient of 450 gauss/cm, gradient magnetic fields of 6.3 mT/m or less and a maximum whole body averaged specific absorption rate (SAR) of 1.2 W/kg for 15 minutes of MRI imaging. MR imaging quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the stent.

### **Stent Identification Information**

<b>Affix Product Label Here or complete:</b>	<b>Affix Product Label Here or complete:</b>	<b>Affix Product Label Here or complete:</b>	<b>Affix Product Label Here or complete:</b>
Product Part # (REF)	Product Part # (REF)	Product Part # (REF)	Product Part # (REF)
Product Lot #	Product Lot #	Product Lot #	Product Lot #
Location of First Stent	Location of Second Stent	Location of Third Stent	Location of Fourth Stent

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Note the location of each stent implant by placing a number in the illustration below.

